MEETING SUMMARY

Tripartite meeting held between the PMDA, EMA, and FDA in Kyoto, Japan to discuss convergence on approaches for the evaluation of antibacterial drugs

The third tripartite meeting yielded significant progress in our discussions on recommended clinical trial designs for evaluating antibacterial drugs and ways to further enhance collaboration in this therapeutic area among the Agencies.

- The discussions at this meeting built on the work of prior meetings leading to further alignment on a number of clinical trial design elements for key indications for antibacterial drugs, such as the approaches for studying antibacterial drugs for uncomplicated gonorrhoea and uncomplicated urinary tract infections.

- The importance of adequately characterizing pharmacokinetic and pharmacodynamic relationships, particularly for drugs that are developed to address serious infections with unmet need was reiterated.

- The importance of obtaining clinical data in pediatric patients was recognized along with the challenges of gathering such data in a timely fashion. The three Agencies will work together to explore options to streamline pediatric antibacterial drug development.

- Monitoring benefit-risk throughout the lifecycle of a product was recognized as an important activity, particularly for drugs approved based on a more limited clinical program.

- To respond to unmet medical needs in the antibacterial area, EMA, FDA and PMDA will continue to work together under their

respective confidentiality agreements to facilitate a single development program that can satisfy the requirements of each of the three Agencies.

- A progress report from the tripartite meetings was presented at The 12th Summit of Heads of Medicines Regulatory Agencies in Kyoto, Japan on October 24, 2017.

- The three Agencies plan to meet again in 2018 to further their work on regulatory convergence.